

# EXHIBIT C

**A. Background and Qualification**

1. I am Professor, Chief of the Addiction Medicine Dual Diagnosis Clinic, Medical Director of Addiction Medicine, and Program Director of the Addiction Medicine Fellowship, in the Department of Psychiatry and Behavioral Sciences at Stanford University School of Medicine. Since 2016, I also hold a Courtesy Appointment in the Stanford University Department of Anesthesiology and Pain Medicine. I began my faculty career at Stanford in 2003. A true copy of my current CV is attached to this Report as Exhibit A.

2. I received my undergraduate degree in Humanities from Yale University in 1989, and my medical degree from Stanford University in 1995, where I also completed a partial residency in Pathology (1997) and a full residency in Psychiatry (2000), as well as a Fellowship in Mood Disorders, Department of Psychiatry and Behavioral Sciences (2002).

3. I have been licensed to practice medicine in the State of California from 1995 to the present. I received the DEA-X waiver to prescribe buprenorphine products in 2013. I am a diplomate of the American Board of Psychiatry and Neurology (2003; recertified, 2013), and a diplomate of the American Board of Addiction Medicine (2013).

4. From 2001 to the present, I have taught medical students, residents, and fellows at Stanford University School of Medicine, on a diversity of topics related to psychiatry, addiction, and pain. For example, from 2004 to the present, I have given annual lectures on addiction medicine within the Practice of Medicine (POM) series for Stanford medical students, including topics such as the neurobiology of addiction, how doctors should intervene when they detect substance use problems, and how to have difficult conversations with patients on the topic of substance use, misuse, overuse, and addiction.

5. I received the Stanford Award for Excellence in Academic Teaching, Department of Psychiatry, in 2014, and again in 2018.

6. In 2013 I founded and became the Training/Program Director for Stanford's Addiction Medicine Fellowship, a post-graduate sub-specialty training year in the treatment of addiction for any medical graduate of a U.S. or Canadian medical school and ACGME-accredited residency. In 2020 I was awarded the ASAM Training Directors Award "for outstanding training in the evaluation, treatment, research and teaching of substance use disorders."

7. As a full time faculty at the Stanford University School of Medicine, I regularly treat patients with addiction to opioids and other substances. For the last 15 years, my clinical practice has included a significant proportion of patients taking prescription opioids for pain relief, for whom such drugs have resulted in misuse, dependence, and addiction. As an integral part of my practice, I work with these patients to develop treatment plans that will address their pain while making appropriate efforts to reduce (taper) or eliminate use of opioids, and/or treat their opioid addiction. Such plans can include non-opioid medications for pain, as well as alternative, non-pharmaceutical modalities, and counseling, with a dual focus on treating the underlying painful condition and the substance use disorder. I frequently collaborate with pain

patients and prescribers.”<sup>16</sup> I began and performed my work in academic detailing before any connection or thought of involvement in litigation, and I continue in this role to counter the false and misleading marketing messages of the Pharmaceutical Opioid Industry.

27. I have substantial experience in the study and teaching on the marketing of opioids, the impacts of such marketing on prescribing habits of physicians, and the effects of market-driven prescribing as a cause of the ongoing opioid epidemic. I have taught extensively at Stanford University and other institutions of higher learning on the ways in which the Pharmaceutical Opioid Industry marketed prescription opioids as both more effective and less addictive than they really are. My lectures have included coverage of overt, aggressive marketing tactics (such as detailing by company sales representatives, coupons for free or discounted opioids, and free lunches or dinners provided to doctors), as well as the Industry’s covert partnerships with, and financial support for, organizations with significant influence on the practice of medicine (e.g., The Joint Commission, The Federation of State Medical Boards, and professional medical societies such as the American Academy of Pain Medicine and the American Pain Society). My lectures have also included discussion of my firsthand experience of these marketing tactics, as well as their continuing impact on several generations of doctors. I have lectured on the Industry’s extensive publications in the peer-reviewed medical literature, explaining that these tactics influence physicians’ opioid prescribing practices. I am frequently asked to peer-review articles for publication in medical journals regarding the influence of the pharmaceutical industry’s marketing on prescribing practices. I have given lectures on these subjects to Stanford undergraduates, Stanford business, law, public health, and medical students, among others. I have also spoken on these topics widely outside of Stanford. In the fall of 2020, I taught at Duke University’s Global Health Institute on the subject of “market driven epidemics.”

28. Since the time of my previous report in this litigation, I have conducted further research concerning the role of pharmacies in the opioid epidemic, and I have also reviewed documents provided by counsel on that subject. These documents and their significance are discussed in Opinion 6, below. Throughout my career I have interacted with pharmacies and pharmacists thousands of times. On any given clinic day I will have interactions with multiple pharmacies and pharmacists pertaining to prescriptions I have written or others have written for patients in my care. The nature of these interactions with pharmacists can be accurately described as a partnership between professionals, with the overarching goal being the safety and best interests of our patients. Due to my role as a frequent prescriber of scheduled pharmaceuticals, I am familiar with the Controlled Substances Act, which includes obligations to prevent unauthorized or illegitimate prescriptions of these potentially dangerous drugs, and to identify and investigate “red flags” which refers to any signs or indications that a particular prescription may be outside of the boundaries of a legitimate medical purpose. I am also aware that “The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”<sup>17</sup>

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<sup>16</sup> Association of Schools & Programs of Public Health (ASPPH) Report, “Bringing Science to Bear on Opioids,” 11/01/2019, [https://aspph-wp-production.s3.us-east-1.amazonaws.com/wp-content/uploads/2019/09/ASPPH.Opioids.FINAL\\_11.01.20191.pdf](https://aspph-wp-production.s3.us-east-1.amazonaws.com/wp-content/uploads/2019/09/ASPPH.Opioids.FINAL_11.01.20191.pdf), at p. 21.

<sup>17</sup> Purpose of issue of prescription, 21 C.F.R. §1306.04(a)

developmental, and environmental factors (nature, nurture, and neighborhood). One of the biggest risk factors for addiction is simple access to addictive drugs. When supply of an addictive drug is increased, more people become addicted to and suffer the harms of that drug. Prescription opioids are as addictive as heroin, and the Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death.

3. Opioid prescribing began to increase in the 1980s and became prolific in the 1990s and the early part of the 21st century, representing a radical paradigm shift in the treatment of pain and creating more access to opioids across the United States.

4. The Pharmaceutical Opioid Industry contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the safety and efficacy of prescription opioids. The Industry disseminated these misleading messages through an aggressive sales force, key opinion leaders, medical school curricula, continuing medical education courses, clinical decision support tools, professional medical societies, patient advocacy groups, the Federation of State Medical Boards, and The Joint Commission.

5. Opioid distributors collaborated with opioid manufacturers and pharmacies to promote sales of opioid pain pills. Such coordinated efforts included programs to give away free samples of opioids, coupons to discount opioids, and promotion of specific opioid products under the guise of education. These activities increased the population of opioid users, dose and duration of opioid use, and the risk of opioid misuse, addiction, dependence, and death.

6. Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. They alone had direct contact with opioid manufacturers and distributors upstream, and patients and prescribers downstream. Their coordinated efforts to "create demand" included advertising specific opioid products at the pharmacy counter, building opioid "Super Stores" to enhance unrestricted flow of opioid pain pills, spreading misinformation about the safety and efficacy of opioid pain pills, partnering with pro-opioid industry advocacy and lobbying organizations, ignoring "red flags" for misuse and diversion including concerns expressed by their own pharmacists, failing to provide pharmacists with sufficient time, resources, or incentives to investigate red flags, and failing to use or analyze their own dispensing data to assist pharmacies in identifying red flags. By increasing and assuring the supply of opioids and failing to provide effective controls against diversion, pharmacies contributed to opioid misuse, addiction, dependence, and death.

7. No reliable scientific evidence shows that long-term opioid therapy is effective for chronic non-cancer pain.

8. The Pharmaceutical Opioid Industry misrepresented that the risk of addiction to prescription opioids is "rare," or "less than 1%," when in fact prescription opioids are as addictive as heroin, and the risk of addiction is far higher than stated by

**TRAINING GAP**

**Current training is seen as insufficient by new users and managers**

- Users expressed that current training does not prepare them for actually working in the pharmacy
- The need to have employees quickly onboarded results in rushed and incomplete training
- Current training is not seen as 'hands on' enough and does not present realistic system usage
- Users estimate it takes 5-7 months after initial training is supposed to be completed before developing full competency
- Senior Technicians and Pharmacy Managers feel that they become de facto teachers to new Technicians which is major burden on them and a drag on pharmacy efficiency
- There is a large deficit in user guidance within the current design which could bridge this training gap

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- I. Defendant Rite Aid failed to effectively control against diversion and undermined Efforts of Pharmacists to Prevent Diversion.
  - i. Rite Aid's role in the opioid epidemic parallels those of Walmart, CVS and Walgreen, as described above. Policies ostensibly designed to control diversion were undermined by incentivized prescribing, understaffing, and poor enforcement, resulting in dispensing of controlled substances in violation of the CSA, and enforcement actions taken by the DEA.
  - ii. In 2009, Rite Aid paid \$5 million to resolve DEA claims of violations of the CSA. "Rite Aid knowingly filled prescriptions for controlled substances that were not issued for a legitimate medical purpose pursuant to a valid physician-patient relationship.... Additionally, the DEA conducted accountability audits of controlled substances at 25 of the 53 stores investigated to determine whether Rite Aid could properly account for Schedule II and III controlled substances purchased and dispensed. *The results of the accountability audits revealed significant shortages or surpluses of the most highly abused drugs, including oxycodone and hydrocodone products, reflecting a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion*

certain criteria are met.”<sup>728</sup> Similarly, Rite Aid’s 2014 OARRS policy listed certain situations in which “the pharmacist must query OARRS,”<sup>729</sup> but those situations would not have been apparent to the pharmacist responsible for making the decision to consult OARRS or not, if the purchaser sought to avoid detection, for example, by shopping at different chain pharmacies. As late as 2019, Rite Aid pharmacists’ failures to use OARRS were described by Mark Obert, Rite Aid’s then-District Manager, as “recurring issues that we need to address,” after multiple Board of Pharmacy inspections at Rite Aid pharmacies revealed deficiencies.<sup>730</sup>

- xi. As with the other Pharmacy Defendants, no Rite-Aid policies called for the company to provide its pharmacists with analyses from their own data sets concerning controlled substance prescriptions or the doctors who prescribed them. This data was available to Rite Aid and should have been provided to the pharmacists, to help them to identify red flags of frequent, high volume, cocktail, or high dose prescribers.
- xii. On March 1, 2013, Rite Aid adopted a corporate monitoring program called the High Alert Review Process.<sup>731</sup> The program listed “prescriber” red flags, including pattern prescribing, large quantities prescribed, and distance traveled; pharmacists were told “in order for a prescription to be valid, there must be a proper patient-prescriber relationship,” and that red flags “MAY indicate that a proper patient-prescriber relationship does not exist.”<sup>732</sup> However, Rite Aid did not provide pharmacists with analysis of its own data to determine the presence or absence of prescriber red flags. Further, the policy directed pharmacists to consult the PDMP “if the prescription or patient is suspicious,”<sup>733</sup> depriving pharmacists of the most appropriate tool to make that determination in the first place.
- xiii. During the same time period, in 2013, Rite Aid continued to undermine the goal of preventing controlled substance diversion by instituting new financial incentives for increased prescriptions. Rite Aid’s “Pay for Performance (P4P)” model adjusted compensation based on whether the pharmacy met certain business goals, such as increasing prescription counts.<sup>734</sup> Specifically, the P4P program stated, “Overall Compensation Performance Summary will reflect an increase in compensation as a result

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<sup>728</sup> Rite\_Aid\_OMDL\_0033915 (emphasis added).

<sup>729</sup> Rite\_Aid\_OMDL\_0077968; e.g., Patient receiving OARRS drugs from multiple prescribers or for more than 12 weeks. These facts could avoid detection through use of multiple pharmacies.

<sup>730</sup> See Rite\_Aid\_OMDL\_0088975, at 0088977

<sup>731</sup> See Rite\_Aid\_OMDL\_0044327 (noting Oxycodone 30mg and Hydrocodone 10/325 are among the drugs Rite Aid “will continue to monitor”).

<sup>732</sup> Rite\_Aid\_MDL\_004379, at 44381 (emphasis in original).

<sup>733</sup> *Id.*, at 44383.

<sup>734</sup> See Rite\_Aid\_OMDL\_0082409.